

### **REMARKS**

Reconsideration of the application in view of the above amendments and following remarks is requested. Claims 1-8, 10, and 25-32 are now in the case. Claims 1, 26 and 27 have been amended. Accordingly, Applicant asserts that the present amendment adds no new matter. Applicant reserves the right to prosecute claims to cancelled subject matter in one or more continuing applications.

### ***MAINTAINED 35 U.S.C. §112, FIRST PARAGRAPH REJECTION***

The Examiner has rejected claims 28-29 and now applied to newly added claims 31-32 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement as introducing new matter is maintained. The claims are alleged to contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

This rejection is vigorously traversed. The Examiner's attention is redirected to page 4, line 22 of the specification, where it is stated that "In addition, certain anti-BCMA-TACI antibody components can bind at least one of: a polypeptide having the amino acid sequence of amino acid residues 39 to 50 of SEQ ID NO:4 and a polypeptide having the amino acid sequence of amino acid residues 78 to 91 of SEQ ID NO:4" (emphasis added). This sentence is also present at page 16, lines 34 – page 17, line 2. Note that this sentence provides an antibody that binds both BCMA (by the fact that it is called a anti-BCMA-TACI antibody) and TACI – where the specific regions of TACI are defined. Merely because the specific region of BCMA is not defined in that specific sentence doesn't mean that it is not supported for binding of BCMA at all – those aspects of the molecule are provided written support in other areas of the specification. One of ordinary skill would understand that the disclosed antibody binds BCMA somehow and TACI in one of the two ways disclosed. Further, the specification is not silent as to how such an antibody would bind BCMA, as implied by the Examiner's rejection. Specifically, the disclosure also states that to be a anti-BCMA-TACI antibody, "the antibody must bind BCMA within a region represented by amino acid residues 1 to 54 of SEQ ID NO:2; amino acid residues 1 to 48 of SEQ ID NO:2; or by amino acid residues 13 to 27 of SEQ ID NO:2 . . . ." page 16, lines 24-27. Thus, there is written support for an antibody that binds BCMA in the range of amino acids 1 to 54 and TACI in the range of 39 to 50 or 78 to 91. It is not required that the two aspects of binding be found in the same sentence in order for that specific cross-reactive antibody to find written support –

yet this is what the Examiner appears to be requiring. Requiring the support to be in the same sentence is an interpretation based on an unlawfully narrowed interpretation of the written support requirements for patentability under § 112, and therefore is properly withdrawn.

*MAINTAINED 35 U.S.C. §103(A) REJECTION*

The Examiner has rejected claims 1-8 and 26-29 under 35 U.S.C. §103(a) as unpatentable over Theill et al. (U.S. Patent No. 6,774,106) in view of Gross et al. (WO 00/40716). This rejection remains respectfully traversed. The Examiner has stated that "based on the low homology between the cysteine rich repeats of the extracellular domains of BCMA and TACI, it would not have been obvious to produce a monoclonal antibody that binds both BCMA and TACI within the claimed cysteine rich repeats of the extracellular domains." Official Action, page 4, lines 8-12. Accordingly, because the present method of use claims utilize an antibody that the Examiner states is non-obvious, the method itself is also non-obvious. The Examiner goes on to imply that the fact that the low homology was presented as attorney argument makes it somehow less persuasive. However, given the Examiner's already stated conclusion of non-obviousness of the antibody utilized in the claimed method, it is respectfully submitted that for this particular factual pattern the information need not be submitted as a declaration to find the claims non-obvious. Withdrawal of this rejection is therefore respectfully requested.

*NEWLY ADDED §112, SECOND PARAGRAPH REJECTION*

The Examiner has rejected claims 1-8, 10 and 25-32 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It appears that the Examiner is objecting to the Applicant being its own lexicographer, which is allowed under patent law. Nevertheless, in a hope to speed prosecution, independent claims 1, 28, and 29 have been amended to recite the use of "antibodies or fragments thereof." This amendment allows one of ordinary skill to fully understand the metes and bounds of the claimed antibodies, as this phrase has a very well know meaning to one of ordinary skill and is considered equivalent to the descriptor "antibody components" used in the specification.

***NEWLY ADDED 35 U.S.C. §112, FIRST PARAGRAPH REJECTION***

The Examiner has rejected claims 1-8, 10, and 25-32 under 35 U.S.C. §112, first paragraph, as enabled for only a specific scope of the present claims. The claims have been amended to a scope which is supported by the teachings of the present specification. Specifically, it is noted that the recited antibody or fragment thereof must bind both TACI and BCMA and any change to this defining structural characteristic would move the antibody (and thus the method using that antibody) outside the scope of the claims. This limitation greatly reduces the concerns put forth by the Examiner about changing of binding ability or breadth of the molecules encompassed by the claimed methods. Furthermore, the present specification teaches a number of specific methods that can be used to determine whether the antibody does indeed bind both TACI and BCMA on page 17, lines 3-23. Because of the specific structural characteristics that the antibodies must have in order to fall within the claims and the guidance provided by the specification to test for this characteristic, the present disclosure fully supports the recited antibodies and the recited methods of use of those antibodies. Accordingly, the newly added rejection has been overcome, and withdrawal of this basis of rejection is respectfully requested.

On the basis of the above amendments and remarks, Applicant believes that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 442-6752.

Please charge any additional fee required or credit any overpayment to Deposit Account No. 26-0290.

Respectfully Submitted,



Michelle L. Lewis  
Registration No. 36,352

Enclosure:

Petition and Fee for Extension of Time  
Customer No. 10117  
ZymoGenetics, Inc.